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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,592	03/19/2004	William Galbraith	P-6007/I	9558
26253 7590 07/26/2010 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER YU, MELANIE J				
ART UNIT 1641		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/804,592

**Applicant(s)**

GALBRAITH, WILLIAM

**Examiner**

MELANIE YU

**Art Unit**

1641

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1.5.6.55 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1.5.6.55 and 58-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's arguments and amendments filed 17 May 2010 have been entered and considered.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 1, 5, 6, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grahnen et al. (The preparation of Ligandin with Glutathione-S-Transferase Activity from Porcine Liver Cytosol by Affinity Chromatography on Bromosulphophthalein-Sepharose, 1977, Eur. J. Biochem., Issue 80, pages 573-580) in view of Spring et al. (US 5,643,721) further in view of Degen et al. (US 5,567,615).

Grahnén et al. teach an apparatus comprising an insoluble support (sepharose column) having a ligand consisting of bromosulphophthalein attached thereto, which is capable of being bindable to albumin, without being exposed to albumin (pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*). Grahnén et al. fail to teach the ligand attached to the support via an epoxy linkage.

Spring et al. teach ligands are attached to an agarose substrate by an epoxy linker (col. 5, lines 50-55), in order to provide a mixture that dries in a film form on the surface to which it is applied.

Degen et al. teach a ligand having a hydroxyl group (col. 12, line 46) attached to a polymer support via an epoxy linker (col. 12, lines 41-47) and therefore teach attachment of a ligand that is epoxy-activated (epoxy linker activates the support, col. 13, lines 44-46), in order to provide attachment of ligands to a polymer substrate.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the apparatus of Grahnén et al., an epoxy linkage between the ligand and the agarose support as taught by Spring et al., in order to provide a simple method of attaching ligands having a hydroxyl group to a substrate by way of a spontaneous covalent attachment as taught by Degen et al. Degen et al. do not specifically teach a bromosulphophthalein ligand being attached to an agarose support. However, Degen et al. teach that epoxy linker attachment is advantageous for ligands having a hydroxyl group and Spring et al. teach that an epoxy linker is advantageous to link ligands to an agarose support. Since bromosulphophthalein comprises a hydroxyl group, Degen et al. teach the epoxy linkage would be a simpler

and advantageous method of attachment of bromosulphophthalein to a substrate, and Spring et al. teach that it would have been obvious for the substrate that the epoxy linker attaches to, to be an agarose support. Therefore an epoxy linker is advantageously used to attach the ligand to the agarose substrate of Grahnen et al.

Although Degen et al. do not specifically teach the ligand being capable of binding to phosphate buffered saline diluted albumin, the claim specifically recites that the ligand that is capable of being bound to phosphate buffered saline diluted albumin is bromosulphophthalein, a salt of bromosulphophthalein or ester of bromosulphophthalein. Since the ligand taught by the prior art is the same ligand that is specifically recited in the claims, the bromosulphophthalein taught by the prior art would have the same structural limitations and therefore the same binding properties as that recited in the claims. The only distinction between applicant's claims and the prior art is recited in the functional language. It is incumbent upon applicant to show that the application disclosed by the prior art is not actually capable of performing such functions. See *In re Ludtke*, 169 USPQ 563 @ 566 (CCPA 1971) and *In re Swinehart et al.*, 169 USPQ 226 @ 229 (CCPA 1971)

With respect to claims 5, 6 and 55, Grahnen et al. teach that the insoluble support is contained in and supported in a column (affinity column with bromosulphophthalein as a ligand, pg. 574, section: *Preparation of Bromosulphophthalein Affinity Column*; and pg. 575, right column, last 2 paragraphs) wherein the support is cross-linked sepharose, which is a type of agarose (pg. 574).

Regarding claims 58-60, the claims recite that after the ligand has been attached to the insoluble support, any remaining active groups have been blocked via exposure to a compound comprising a primary amine and ethanolamine having a pH of 8.0 alkaline solvent. However this limitation is not claimed as part of the apparatus and is drawn to a method of making the support. The prior art references of Grahnen et al., Spring et al. and Degen et al., as described above, teach the structural limitations required for the claims and therefore read on the claimed invention.

### ***Response to Arguments***

2. Applicant's arguments filed 10 December 2009 have been fully considered but they are not persuasive.
3. Applicant argues that Grahnen et al, Spring et al. and Degen et al. fail to teach the ligand being bindable to phosphate buffered saline diluted albumin.

Applicant's argument is not persuasive because the rejected claims are drawn to a product of a device comprising the structural limitations of a bromosulphothalein ligand attached to a support through an epoxy linker. The prior art teaches the same bromosulphothalein ligand and therefore has the same structural limitations and the same binding properties as the claimed ligand. Therefore the bromosulphothalein taught by the prior art would also be capable of binding a phosphate buffered saline diluted albumin as required by the claims. Furthermore, applicant does not suggest how the ligand taught by the prior art is structurally different from the claimed ligand such that the ligand of the prior art does not bind to a phosphate buffered saline diluted albumin. Since the final product taught by the combination of prior art references has

the same structural limitations that are recited by the instant claims, the claimed invention is obvious over the prior art.

***Conclusion***

4. No claims are allowed.
5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MELANIE YU** whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/  
Primary Examiner, Art Unit 1641